

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Soo-Hyun Kim *et al.*

Serial No.: 10/578,943

Group No.: 1647

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Examiner:

Entitled: **Compositions And Methods For Regulation Of Tumor Necrosis Factor-Alpha**



INFORMATION DISCLOSURE STATEMENT

MS Amendment

Commissioner for Patents

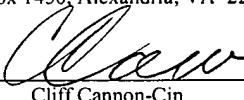
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Dated: March 5, 2008

By: 

Cliff Cannon-Cin

Dear Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. § 1.56 and § 1.97. The Examiner is requested to make these citations of official record in this application.

The following citations are referred to in the body of the Specification:

- U.S. Patent No. 6,277,969 to Le *et al.*, "Anti-TNF Antibodies And Peptides Of Human Tumor Necrosis Factor," 2001;
- U.S. Patent No. 6,448,380 to Rathjen *et al.*, "Tumor necrosis factor antibodies," 2002;
- Banda *et al.*, "Mechanisms of effects of complement inhibition in murine collagen-induced arthritis," *Arthritis Rheum*, 46:3065, 2002;
- Banda *et al.*, "Mechanisms of inhibition of collagen-induced arthritis by murine IL-18 binding protein," *J Immunol*, 170:2100-2105, 2003;

- Bendele *et al.*, "Combination benefit of treatment with the cytokine inhibitors interleukin-1 receptor antagonist and PEGylated soluble tumor necrosis factor receptor type I in animal models of rheumatoid arthritis," *Arthritis Rheum*, 43:2648-2659, 2000;
- Bernot *et al.*, "A transcriptional map of the FMF region" *Genomics*, 50:147-160, 1998;
- Cohen, "Systemic Autoimmunity," in Paul (ed.) Fundamental Immunology, Lippincott-Raven Publishers: Philadelphia, pp. 1067-1088, 1999;
- Dahl *et al.*, "Identification of a novel gene expressed in activated natural killer cells and T cells," *J Immunol*, 148:597-603, 1992;
- Davis *et al.*, "Treatment of rheumatoid arthritis with PEGylated recombinant human soluble tumour necrosis factor receptor type I: a clinical update," *Ann Rhem Dis*, 59Suppl1:i41-3, 2000;
- Faggioni *et al.*, "IL-18-binding protein protects against lipopolysaccharide- induced lethality and prevents the development of Fas/Fas ligand-mediated models of liver disease in mice," *J Immunol*, 167:5913-5920, 2001;
- Firestein, "Rheumatoid Arthritis," in Scientific American Medicine, 2000;
- Gracie *et al.*, "A proinflammatory role for IL-18 in rheumatoid arthritis," *J Clin Invest*, 104:1393-1401, 1999;
- Panelli *et al.*, "Gene-expression profiling of the response of peripheral blood mononuclear cells and melanoma metastases to systemic IL-2 administration" *Genome Biol*, 3(7):research0035.1-0035.17, 2002; and
- Steed *et al.*, "Inactivation of TNF signaling by rationally designed dominant-negative TNF variants," *Science*, 301:1895-1898, 2003.

The following references were cited in the International Search Report of the parent International Application No. PCT/US2004/037578 (our file UTCA-08870):

- International Publication No. WO 02/059260 of Tang *et al.*, "Novel nucleic acids and polypeptides," 2002, provided by WIPO; and
- Neto *et al.*, "Shotgun sequencing of the human transcriptome with ORF expressed sequence tags," *Proc Natl Acad Sci USA*, 97:3491-3496, 2000.

Additionally, Applicants have become aware of the following references, which may be material to patentability of the invention:

- U.S. Patent No. 6,572,852 to Smith *et al.*, “Method for suppressing inflammatory responses by administering TNFR,” 2003;
- U.S. Patent No. 6,706,491 to Chang *et al.*, “Reagents and methods for identifying and modulating expression of genes regulated by P21,” 2004;
- U.S. Patent No. 6,989,262 to Bejanin *et al.*, “Plasmin variants and uses thereof,” 2006;
- Publication No. US 2003/0087270 of Schlegel *et al.*, “Novel genes, compositions, kits and methods for identification, assessment, prevention, and therapy of cervical cancer,” 2003;
- Publication No. US 2003/0092616 of Matsuda *et al.*, “STAT6 activation gene,” 2003;
- Publication No. US 2003/0148316 of Lipford *et al.*, “Methods and compositions relating to plasmacytoid dendritic cells,” 2003;
- Publication No. US 2003/0154032 of Pittman *et al.*, “Methods and compositions for diagnosing and treating rheumatoid arthritis,” 2003;
- Publication No. US 2005/0048490 of Azimzai *et al.*, “Proteins associated with cell growth, differentiation and death,” 2005;
- Publication No. US 2005/0130145 of Yue *et al.*, “Secreted proteins,” 2005;
- Publication No. US 2005/0208496 of Ohtani *et al.*, “Methods of testing for bronchial asthma or chronic obstructive pulmonary disease,” 2005;
- Publication No. US 2006/0088532 of Alitalo *et al.*, “Lymphatic and blood endothelial cell genes,” 2006;
- International Publication No. WO 01/64886 of Gaiger *et al.*, “Compositions and methods for the detection, diagnosis and therapy of hematological malignancies,” 2001, cover page of 1252 page document provided, complete document will be provided at the Examiner’s request;
- International Publication No. WO 02/083898 of Bejanin *et al.*, “Full-length human cDNAs encoding potentially secreted proteins,” 2002, cover page of 735 page document provided, complete document will be provided at the Examiner’s request;

- International Publication No WO 02/096943 of Honda *et al.*, “STAT6-activating genes,” 2002, cover page of Japanese document provided, with US 2003/0092616 listed as English translation;
- International Publication No. WO 03/080640 of Alitalo *et al.*, “Lymphatic and blood endothelial cell genes,” 2003;
- International Publication No. WO 2005/016962 of Abbas *et al.*, “Compositions and methods for the treatment of immune related diseases,” 2005;
- International Publication No. WO 2006/071088 of Yoon *et al.*, “Markers for the diagnosis of AML, B-ALL and T-ALL,” 2006;
- International Publication No. EP 1487857 of Alitalo *et al.*, “Lymphatic and blood endothelial cell genes,” cover pages of document replaced by WO 03/080640;
- GenBank Accession No. AAH09401 GI:14424787, 2001;
- GenBank Accession No. AAH18782 GI:17511868, 2001;
- GenBank Accession No. AAS80144 GI:46095218, 2003; and
- Strausberg *et al.*, “Generation and initial analysis of more than 15,000 full-length human and mouse cDNA sequence,” *Proc Natl Acad Sci USA*, 99:16899-16903, 2002.

Also included for the Examiner’s convenience are copies of printed publications in which one or more of Applicants are co-authors. These citations have been included for the sake of completeness:

- U.S. Patent No. 6,605,280 to Novick *et al.*, “Interleukin-18 binding proteins, their preparation and use for blocking the activity of IL-18,” 2003;
- Dinarello and Kim, “IL-32, a novel cytokine with a possible role in disease,” *Ann Rheum Dis*, 65(Suppl III):iii61-iii64, 2006;
- Joosten *et al.*, “IL-32, a proinflammatory cytokine in rheumatoid arthritis,” *Proc Natl Acad Sci USA*, 103:3298-3303, 2006;
- Kim *et al.*, “Interleukin-32: A cytokine and inducer of TNF α ,” *Immunity*, 22:131-142, 2005; and
- Plater-Zyberk *et al.*, “Therapeutic effect of neutralizing endogenous IL-18 activity in the collagen-induced model of arthritis,” *J Clin Invest*, 108:1825-1832, 2001.

This Information Disclosure Statement under 37 C.F.R. § 1.56 and § 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: March 5, 2008

By: *Christine A. Lekutis*
Christine A. Lekutis
Registration No. 51,934

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
415.904.6500